

## **II. REMARKS**

### **Preliminary Remarks**

This response is being timely filed, as it is being filed with a petition for an extension of time to reply in the third month with the requisite fee.

As originally filed, this application contained a total of nine claims, and the applicant has not amended those claims in this response. Therefore, after entry of this response, claims 1-9 will be pending in this application. The applicant has amended various portions of the specification in reply to the examiner's objections, as will be explained below in further detail. No new matter is believed to have been introduced by the foregoing amendment.

### **Objections to the Specification**

The examiner objected to the specification as allegedly containing improper browser executable code. The examiner also objected to the specification as allegedly failing to comply with the requirements for patent applications containing sequence listing disclosures.<sup>1</sup>

With respect to the objection based on the inclusion of browser executable code, the applicant has amended the specification to remove the hyperlinks and, where applicable, to insert generic descriptions of how the information may be accessed. The applicant believes that the referenced electronic databases are well known to those of skill in the art, and that the generic descriptions provided in this response are readily derived from the original hyperlinks themselves. Therefore, the applicant respectfully requests that the objection be withdrawn.

With respect to the objection based on the sequence listing rules, the applicant has amended the specification to remove the sequence listing previously shown on page 18. That sequence listing was included in the application as part of an example of the GenBank file format, so that the reader would be able to appreciate the various fields and types of data contained in such a file. As those of skill in the art will appreciate, the applicant might have presented any one of a number of exemplary GenBank data files instead of that for baboon alcohol dehydrogenase. Therefore, because the actual sequence listing is not related to or in

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<sup>1</sup> In addition to the objection, the Examiner notes in the second paragraph of the official action that "the computer readable format of the sequence listing was corrected by STIC personnel." However, no CRF has been submitted for this application. During a teleconference with the applicant's representative, Examiner Zeman agreed that no CRF had been submitted and stated that the comment was in error.

any way descriptive of the applicant's claimed invention, the applicant has simply removed it. (Moreover, the applicant notes that if the sequence listing was amended to comply with the Patent Office rules of practice, it would negate the purpose of its original inclusion, because the sequence would no longer be a faithful reproduction of the GenBank format.) Accordingly, the applicant respectfully submits that the objection is moot and requests that it be withdrawn.

Patentability Remarks

35 U.S.C. § 102(e)

Claims 1-9 were rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by Tomonaga, *et al.*, U.S. Patent No. 6,199,017 (hereinafter the "'017 patent"). The examiner's position is that the '017 patent "provides systems and computer programs for the management and display of metabolic pathways. [...] Information from literature databases are linked, which includes information of gene sequences." Claims 1-9 were also rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Tomonaga, *et al.*, WO96/29659, which is the earlier international publication of the international application that matured into the '017 patent. For brevity, and because the technical content of the two references is the same, the applicant responds to both rejections as follows.

The applicant respectfully disagrees and traverses the rejections for at least the following reasons.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The applicant submits that the '017 patent does not disclose each and every element of the applicant's claimed invention.

Claim 1 recites a data processing system "for managing and presenting information derived from a differential expression of genetic information." The system includes "an association mechanism which links "previously generated sets of affected sequence data to biological catalyst identifiers." The sequence data "represent[s] a direction and a magnitude of regulation of each one of a number of different nucleic acid sequences." The applicant submits that at least those features are not disclosed in the '017 patent.

The '017 patent discloses a system for determining chemical structures of compounds based on bond lengths. It also includes a program element for displaying three-dimensional chemical structures of biological compounds, and relational databases for determining what receptors and enzymes the compound binds to. While the system of the '017 patent may be designed to store and process information very indirectly derived from genetic sequences (in the sense that biochemicals of the sort to which the '017 patent pertains are all ultimately encoded in genetic sequences), the applicant submits that that information is not "derived from a differential expression of genetic information" (emphasis added) as is recited in claims 1 and 4. Furthermore, the applicant respectfully submits that there is no disclosure in the '017 patent as to recording or processing the magnitude of regulation of particular genetic sequences or linking that information with particular biological catalysts.

Claim 4 recites a method of managing and presenting information "derived from a differential expression of genetic information." The method includes "linking sets of previously generated sequence data with biological catalyst identifiers, [the] sequence data representing a direction and a magnitude of regulation of each one of a number of nucleic acid sequences." Therefore, the applicant respectfully submits that the arguments presented above with respect to claim 1 also apply to claim 4.

In view of the above, the applicant respectfully submits that the '017 patent (and its WO equivalent) cannot, as a matter of law, properly anticipate independent claims 1 and 4, or the claims that depend from them. Accordingly, the applicant respectfully requests that the rejection be withdrawn.

Claims 1-9 were rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by Thalhammer-Reyero, U.S. Patent No. 5,980,096 (hereinafter the "'096 patent"). The examiner's position is that the '096 patent "discloses computer based systems and programs for organizing, managing, and displaying data involved in metabolic pathways." In particular, the examiner asserts that "information from gene expression profiles, once validated and assigned a function can also be included." The applicant disagrees and respectfully traverses.

The '096 patent discloses another biochemical modeling and simulation program. In general, the disclosed program is designed to simulate various biochemicals and macromolecules as they interact with one another to construct a "working" model of a

biological pathway. As is also the case in the '017 patent, the '096 patent does not disclose a method or system for managing and presenting information "derived from a differential expression of genetic information" as a "map having a matrix of regions and locations within each region," as recited in claims 1 and 4.

Moreover, whether or not "information from gene expression profiles...can also be included" in the system of the '096 patent as the examiner asserts (and the applicant is not entirely sure of what sort of "information" the examiner has in mind), the applicant submits that the ability to input information from single sets of genetic expression data is not equivalent to the ability to process data derived from differential expression of genetic information, nor does it imply the ability to create a map of the type recited in claims 1 and 4. The applicant respectfully submits that neither of those capabilities is disclosed in the '096 patent; in fact, there is no "association mechanism" as recited in claim 1 or task of linking sequence data with catalyst identifiers, as recited in claim 4.

In view of the above, the applicant respectfully submits that the '096 patent cannot, as a matter of law, properly anticipate independent claims 1 and 4, or the claims that depend from them. Accordingly, the applicant respectfully requests that the rejection be withdrawn.

Claims 1-9 were rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by Hogue, *et al.*, U.S. Application Publication No. 2002/0072865 (hereinafter "the '865 publication"). Irrespective of the examiner's position as to the disclosures of the '865 publication, the applicant respectfully submits that the rejection is not properly made under § 102(e) and, thus, traverses the rejection.

The applicant respectfully submits that the effective § 102(e) date of the '865 publication is later than the effective filing date of this application. As to the effective filing date of this application, this application claims priority to U.S. Provisional Application No. 60/121,432, filed February 23, 1999, and is the national phase of PCT/US00/04338, filed February 22, 2000. Therefore, this application has an effective filing date under 35 U.S.C. § 365(c) of **February 22, 2000**, and the applicant submits that this application is also entitled to the benefit of the **February 23, 1999** filing date of the provisional application. See MPEP (8<sup>th</sup> ed., R1) § 706.02(a) on page 700-21, column 1, "DETERMINING THE EFFECTIVE FILING DATE OF AN APPLICATION," paragraph (A).

As to the effective § 102(e) date of the '865 publication, the applicant submits that the '865 publication itself has an effective § 102(e) date of August 7, 2001, more than a year after the applicant's effective filing date. The applicant directs the examiner's attention to MPEP (8<sup>th</sup> ed., R1) § 706.02(f)(1) on page 700-36 at Example 9, where this type of situation is explained. (A flow chart is provided on page 700-37.) Essentially, although the '865 publication claims priority to an international application, PCT/CA00/00124, that international application was filed on February 11, 2000, before November 29, 2000. Therefore, the '865 publication has a § 102(e) date identical to its § 111(a) filing date, August 7, 2001.

Accordingly, the applicant respectfully requests that the rejection be withdrawn.

Although the foregoing constitutes a complete response to the rejection, the applicant notes that in a situation like this, an international application is prior art under §§ 102(a) or 102(b) as of the date of its publication. For that reason, the applicant also notes that PCT/CA00/00124 was published as WO 00/48092 on August 17, 2000, which is also after the applicant's effective filing date. Therefore, the international publication of the '865 publication may not be used as prior art against the present application.

#### 35 U.S.C. § 102(b)

Claims 1-9 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Schilling, *et al.*, *Proc. Natl. Acad. Sci.* 95, pp. 4193-4198, April 1998 (hereinafter "the Schilling reference"). The examiner's position is that the Schilling reference discloses "systems and programs for organizing, managing and displaying data involved in metabolic pathways" allowing for various types of map displays. The examiner also asserts that "information from gene expression profiles...can be included" and that "substrate, catalyst and product can all be included." The applicant respectfully disagrees and traverses the rejection for at least the following reasons.

The Schilling reference discloses a generic technique for the mathematical modeling of a metabolic pathway using techniques of linear algebra. The disclosed technique equates a metabolic pathway to a system of algebraic mass balance equations which can be solved simultaneously to yield information on the overall state of the system. By way of example, the Schilling reference examines the mass balances involved in the metabolic processes underway within a red blood cell.

The applicant respectfully submits that the so-called “maps” present in the Schilling reference are provided by the authors to explain the basic mathematics and do not represent the output of any analytical process disclosed in the reference.

Furthermore, the applicant respectfully submits that the disclosures of the Schilling reference are entirely focused on analyzing the mass balances in metabolic pathways. There is no disclosure in the Schilling reference of a method or system for managing and presenting information derived from “differential expression of genetic information” in which a map is generated by linking sequence data to biological catalyst identifiers. The applicant respectfully submits that mass balance equations alone do not link data that represents the direction and magnitude of regulation of a particular genetic sequence with biological catalyst identifiers. In fact, the applicant fails to see where and how the examiner proposes to store sequence data in the algebraic matrices (*i.e.*, the systems of linear equations) disclosed in the Schilling reference.

Accordingly, the applicant respectfully requests that the rejection be withdrawn.

ROGERS -- 09/914,200

Client/Matter: 070441-0283207

### **III. CONCLUSION**

In view of the foregoing, the applicant respectfully submits that this application is in condition for allowance. A timely notice to that effect is respectfully requested. If questions relating to patentability remain, the examiner is invited to contact the undersigned to discuss those questions.

Please charge any fees associated with the submission of this paper to Deposit Account Number 033975. The Commissioner for Patents is also authorized to credit any over payments to the above-referenced Deposit Account.

Respectfully submitted,

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